



U.S. Food and Drug Administration

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Increasing Awareness of Acetaminophen via Pharmacy-Generated Prescription (Rx) Container Labeling

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Medical Affairs and Clinical Research

November 16, 2010



Acetaminophen:

Important Ingredient in OTC + Rx Medicines

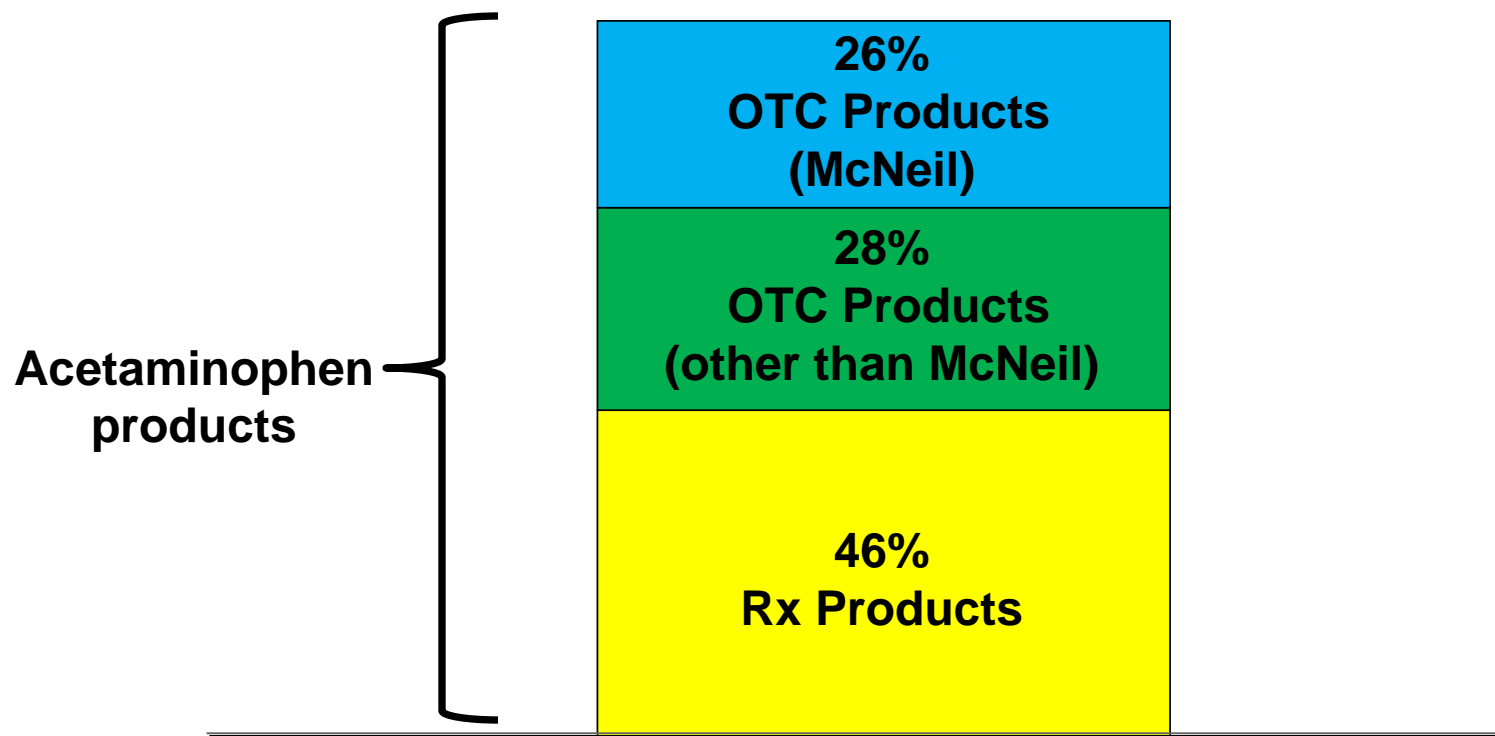
- One of the most widely used and most important medicines in the United States.
- When used according to the label directions has well-established record of safety and efficacy.
- Although very rare in the context of its broad usage, overdose can be toxic and lead to acute liver failure.

Gaps in Awareness

- Patients may not recognize that acetaminophen:
 - is the active ingredient
 - is commonly abbreviated (ex. “APAP”) on Rx pharmacy generated labels^{1,2}
 - common to many over-the-counter (OTC) and prescription (Rx) medicines^{3,4}
 - use from multiple acetaminophen-containing medicines places them at risk for overdose⁵
 - overdose places them at risk for liver injury

1. Institute for Safe Medicines Practices. “PA State Board of Pharmacy Newsletter Winter 2007-2008 (page 4-5)
2. National Association Boards of Pharmacy July 15 2010 <http://www.nabp.net/news/nabp-recommends-boards-of-pharmacy-prohibit-use-of-acetaminophen-abbreviation> (accessed 11/2/10)
3. Fosnocht D. et al. Emerg. Med. J.2008;25:213-216
4. Stumpf JL, et al. Journal of the American Pharmacist Association. 2007;47:1:35-41
5. Letter from S. Galson to State Boards of Pharmacy, 2004;
<http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM171903.pdf>

Increasing Acetaminophen Ingredient Awareness Needs to Involve Multiple Stakeholders



"APAP" Appears on Pharmacy-Generated Rx Container Labels

RXDC EPS TRAIN 01 001 (817)-246-6760
9560 CLIFFORD STREET FORT WORTH TX 76109

6601235 null Smith, Rance MD

Hill, Tray 05/28/09
**TAKE ONE TABLET BY MOUTH EVERY
FOUR HOURS AS NEEDED FOR PAIN.**

Ultracet Tab Mcne

NO REFILLS 28 TAB Drug Exp 5/28/2010

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO
ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.

RXDC EPS TRAIN 01 001 (817)-246-6760
9560 CLIFFORD STREET FORT WORTH TX 76109

6601236 null Smith, Rance MD

Hill, Tray 05/28/09
**TAKE ONE TABLET BY MOUTH EVERY
FOUR HOURS AS NEEDED FOR PAIN.**

Tramadol Apap Tab Par
PAR GENERIC DISPENSED
NO REFILLS 28 TAB Drug Exp 5/28/2010

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO
ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.

RXDC EPS TRAIN 01 001 (817)-246-6760
9560 CLIFFORD STREET FORT WORTH TX 76109

4401051 null Smith, Rance MD

Hill, Tray 05/28/09
**TAKE ONE TABLET BY MOUTH EVERY
FOUR HOURS**

Hydrocodone Apap 10-325 Tab Wats
WATSON LAB GENERIC DISPENSED
NO REFILLS 28 TAB Drug Exp 5/28/2010

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO
ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.

RXDC EPS TRAIN 01 001 (817)-246-6760
9560 CLIFFORD STREET FORT WORTH TX 76109

4401050 null Smith, Rance MD

Hill, Tray 05/28/09
**TAKE ONE TABLET BY MOUTH EVERY
FOUR HOURS AS NEEDED FOR PAIN.**

Hydrocodone Apap 7.5-65 Tab Mall
MALLINCKRODT GENERIC DISPENSED
NO REFILLS 28 TAB Drug Exp 5/28/2010

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO
ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.

RXDC EPS TRAIN 01 001 (817)-246-6760
9560 CLIFFORD STREET FORT WORTH TX 76109

4401052 null Smith, Rance MD

Hill, Tray 05/28/09
**TAKE ONE TABLET BY MOUTH EVERY
FOUR HOURS AS NEEDED FOR PAIN.**

Propoxyphene Apap 100-65 Tab Teva
TEVA PHARM GENERIC DISPENSED
NO REFILLS 28 TAB Drug Exp 5/28/2010

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO
ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.

RXDC EPS TRAIN 01 001 (817)-246-6760
9560 CLIFFORD STREET FORT WORTH TX 76109

6601237 null Smith, Rance MD

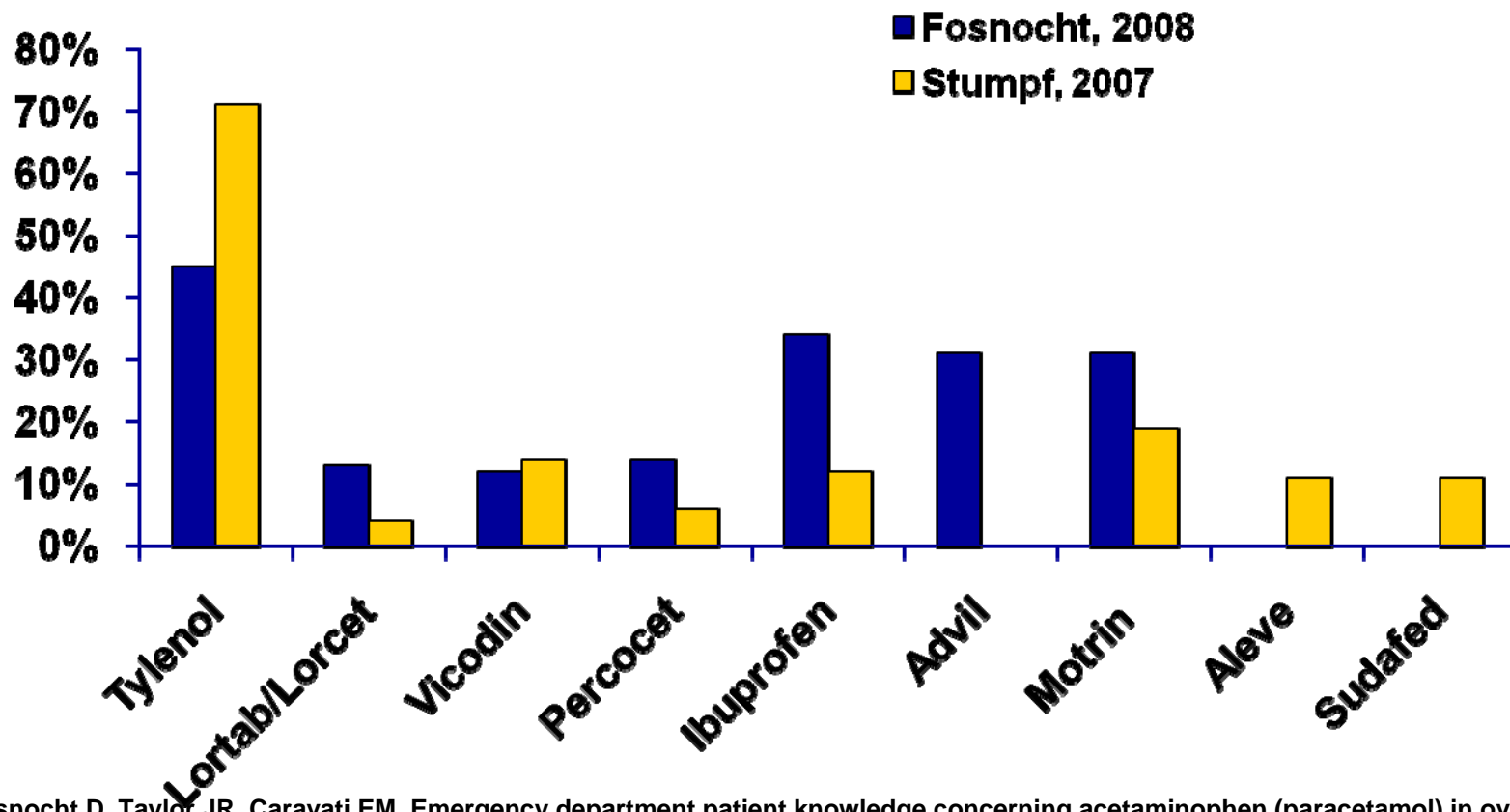
Hill, Tray 05/28/09
**TAKE ONE TABLET BY MOUTH EVERY
FOUR HOURS AS NEEDED FOR PAIN.**

Butorphanol Apap/Caf Tab West
WEST-WARD GENERIC DISPENSED
NO REFILLS 28 TAB Drug Exp 5/28/2010

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO
ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED.

Variable Awareness of Analgesic / Antipyretic Ingredients in OTC and Rx Products

Does this product contain acetaminophen? – “Yes”



1. Fosnocht D, Taylor JR, Caravati EM. Emergency department patient knowledge concerning acetaminophen (paracetamol) in over-the-counter and prescription analgesics. *Emerg. Med. J.* 2008;25:213-216
2. Stumpf JL, Skyles AJ, Alaniz C, et al. Knowledge of appropriate acetaminophen doses and potential toxicities in an adult clinical population. *Journal of the American Pharmacist Association.* 2007;47:1:35-41
3. Chen L, Schneider S, Wax P. Knowledge about acetaminophen toxicity among emergency department visitors. *Vet Human Toxicology.* 2002; 44: 370-373.

Acetaminophen is Commonly Abbreviated as “APAP” on Pharmacy-Generated Rx Container Labels

- Standards lacking for completely spelling out “acetaminophen”
- Limited space in drug name fields of pharmacy labeling systems and on the Rx container label often prevent the use of complete generic drug names on the prescription generated Rx container label¹
- If only a Rx Brand name is used, the container label may not list acetaminophen or “APAP” at all
- Standard practice unclear for content, selection, and prioritization of auxiliary warning labels

Institute for Safe Medicines Practices. “Pennsylvania State Board of Pharmacy Newsletter Winter 2007-2008 (page 4-5): “ Don’t Hide the Acetaminophen” Letter from Steven Galson to State Boards of Pharmacy, Acetaminophen Hepatotoxicity and Nonsteroidal Anti-inflammatory Drug (NSAID)-related Gastrointestinal and Renal Toxicity (Jan 22, 2004) available at <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM171903.pdf>

Chen L, et al. Knowledge about acetaminophen toxicity among emergency department visitors. Vet Human Toxicology. 2002; 44: 370-373.

Improving Pharmacy-Generated Rx Container Labels to Increase Acetaminophen Awareness

- Support expressed from multiple stakeholders for removing “APAP”
 - FDA , National Association Boards of Pharmacy (NABP), healthcare providers, retailers, pharmacy label system companies, etc.
- Completely spell out “acetaminophen” (Rx branded and unbranded medicines)
- Auxiliary warning label
 - Content: consistent with OTC drug facts concomitant use warning
 - Example: Contains acetaminophen. Do not use with any other drug containing acetaminophen (prescription or nonprescription).
 - Selection: a single acetaminophen use warning (see above)
 - Prioritization: use warning within top 3 hierarchy
 - Add acetaminophen ingredient icon

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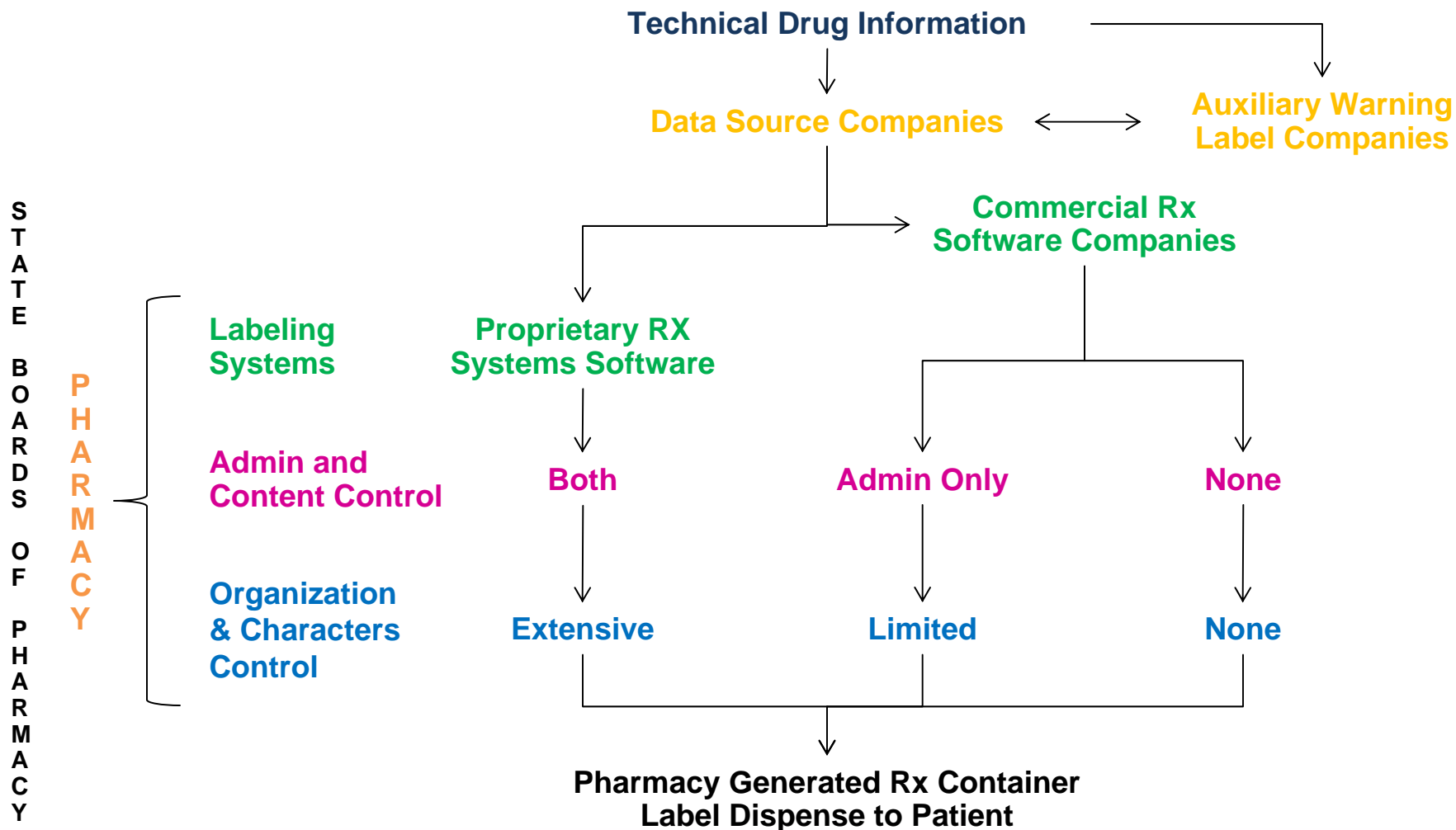


Contains acetaminophen. Do not use with any other drug containing acetaminophen (prescription or nonprescription).



Key Elements

Pharmacy-Generated Rx Container Label



First DataBank: “APAP” Revision Oct 2010

- Will replace “APAP” in the Brand Name and Label Name of such products with:
 - Acetaminophen
 - Or alternate abbreviations:
 - Acetaminophn, Acetaminoph, Acetaminop, Acetamin, Acetam

Anticipate National Council for Prescription Drug Programs (NCPDP) Guidance

- Developing guidance (white paper) on new labeling standard for pharmacy generated labels for Rx acetaminophen-containing medicines
- Anticipate approval of new guidance in 2011
 - Always completely spell out acetaminophen
 - Standard practice for content, selection, and prioritization of auxiliary warning labels

Increasing Awareness of Acetaminophen via Pharmacy-Generated Prescription (Rx) Container Labeling

Continued Progress and Stakeholder Support

- Ensure support of state boards of pharmacy
- Encourage continued removal of “APAP” from data sources
- Promote change to completely spell out acetaminophen
- Establish standard practice for content, selection, and prioritization of acetaminophen auxiliary warning label
- Evaluate acetaminophen ingredient icon for all OTC and Rx labels
- Sustain stakeholder engagement